

## EXHIBIT 234

### CLIA NOTICE OF NONCOMPLIANCE AND PROPOSED SANCTION(S) (NO IMMEDIATE JEOPARDY)

(Date)

Director Name

CLIA Name

Address

City, State, ZIP Code

Dear (CLIA Director Name):

Re: CLIA Number: (CLIA Number)

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) and bill for services provided to Medicare beneficiaries and Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA requirements at Title 42 Code of Federal Regulations, Part 493.

This is to inform you that the survey conducted by the (State survey agency's name) on (date) has identified noncompliance with the CLIA Conditions as specified on the attached list and citations of statutory and regulatory authority, and the attached Form CMS-2567, Statement of Deficiencies and Plan of Correction. This noncompliance does not pose immediate jeopardy to patients served by the laboratory. If these deficiencies remain uncorrected, we will impose, as of (projected effective date and duration) the following alternative sanctions):

(Specify which sanctions are to be imposed. If a civil money penalty will be imposed, state the amount of the penalty and specify whether the amount is for each day of noncompliance or each violation. Also clarify that the penalty amount is not collected prior to the hearing, but will accrue until the outcome of the hearing or correction of the noncompliance. Explain that civil money penalty amounts may be increased or decreased prior to the hearing if noncompliance worsens, e.g., if an immediate jeopardy situation develops or is partially corrected.)

(If State on-site monitoring is imposed, include the expected frequency and length of time the monitor will be in the laboratory. Include also the hourly rate that will apply.)

(If a directed plan of correction is imposed, include the letter which specifically addresses the imposition of this sanction.)

(Name)

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(Date)

(If principal sanctions, i.e., suspension, limitation, or revocation of the CLIA certificate) are proposed, note that they will be effective following the administrative hearing decision, if the Centers for Medicare & Medicaid Services prevails in its determination of noncompliance.)

Within 10 days after the receipt of this notice, you may submit to (State survey agency's name) or to CMS written evidence or any other information against the imposition of these (this) sanction(s). You may also request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative, and must contain the following information:

1. The specific issues or findings with which you disagree; and
2. The specific basis for contending that the State agency's or CMS' findings of noncompliance are incorrect. Additional evidence may also be presented at the hearing, and you may be represented by counsel.

Administrative hearings are conducted by the Departmental Appeals Board of the Department of Health and Human Services (DHHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, DHHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

The alternative sanctions listed above will be effective prior to the hearing or until CMS determines that the noncompliance on which the sanctions are based has been corrected.

Sincerely yours,

Associate Regional Administrator  
(or its equivalent)

Enclosure

cc: State Agency